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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/983,067	10/23/2001	Akio Inoue	1752-0151P	8894

2292 7590 05/25/2005

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EXAMINER

MAYER, SUZANNE MARIE

ART UNIT PAPER NUMBER

1653

DATE MAILED: 05/25/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/983,067

Applicant(s)

INOUE ET AL.

Examiner

Suzanne M. Mayer, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 09 December 2004.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-17 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-17 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 11/12/02; 1/15/03; 1/23/03; 1/05/05
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Claim Status***

1. Claims 1-17 are pending in this application. Claim 18 has been cancelled by Applicant.

### ***Information Disclosure Statement***

2. The information disclosure statements (IDS) submitted on April 24, 2002; May 7, 2002; October 17, 2002; November 12, 2002; January 15, 2003; January 23, 2003 and January 5, 2005 have been considered by the examiner. See signed and attached PTO-1449's.

### ***Priority***

3. Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file. Receipt of English translations of each foreign priority document is acknowledged.

### ***Response to Arguments***

4. Acknowledgement of the submission of a new abstract is made. The new abstract overcomes the objection to the abstract as presented in the previous office action and thus has been withdrawn.
5. Applicant's arguments, see Remarks, filed December 9, 2004, with respect to the rejections of claims 1-18 under 35 U.S.C § 112 2<sup>nd</sup> and 102(a) have been fully

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considered and are persuasive. Therefore, the rejections have been withdrawn.

However, upon further consideration, new grounds of rejection is made in view of Rothschild et al. ((a) U.S. 6,306,628 and (b) US 2005/0032078) and Allen et al. (Analyt. Biochem., April 10, 1999).

### ***Claim Rejections - 35 USC § 102***

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 1-17 are rejected under 35 U.S.C. 102(e) as being anticipated by Rothschild et al. ((a) U.S. 6,306,628 and (b) US 2005/0032078) Rothschild et al. teach a method of *in vitro* cell free protein synthesis of nascent polypeptides which are labeled. However, in order for the nascent polypeptide to obtain its label, a misaminoacylated tRNA with said label is added to the translation reaction system. The tRNA thus transfers said label to the nascent protein. The labeled tRNA is selected according to the choice of purification methods to be utilized for the protein, selected from the following: affinity chromatography, magnetic bead separation, chemical extraction, etc., or a combination of these techniques (see paragraph [0029] in

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Rothschild et al. (b) and column 7, lines 7-23 in Rothschild et al. (a)). Examples are given such as in paragraph [0165] of Rothschild et al. (b) where tRNA<sup>fmet</sup> is used to attach a fluorescent marker to the protein and (obviously the tRNA<sup>fmet</sup>) which can subsequently be isolated by streptavidin affinity purification methods. A variety of other affinity markers that are incorporated into the reaction system by introduction of the labeled misaminoacylated tRNA into the reaction system is outlined and described on p. 19 for Rothschild et al. (b) and under Affinity Markers and in column 35 line 25 for Rothschild et al. (a).

Example 16, p. 33, further teaches a triple marker system which labels the tRNA with three different labels which is incorporated into the nascent protein upon introduction of this tRNA into the reaction system. Finally, p. 26 paragraph [0221-0229] for Rothschild et al. (b) and columns 48-50 Rothschild et al. (a) describes the use of the invention in kits with appropriately labeled tRNA's in the cell free reaction system.

8. Claims 1, 3, and 8-10 rejected under 35 U.S.C. 102(b) as being anticipated by Allen et al (cited on the IDS from Jan. 15, 2003). Allen et al. teach the *in vitro* transcription and translation of a his-tagged RegA69 protein. Thus at least one protein component of the reaction system has been labeled by an affinity marker where the product can be recovered via various nickel, zinc or cobalt columns.

***Conclusion***

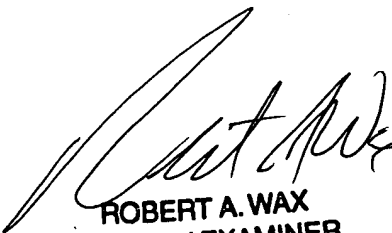
9. No claim is allowed.
10. The Examiner would like to notify Applicant that there appears to be patentable subject matter within this pending application. However, the scope of the claims are not commensurate with what is patentable (e.g. limiting the claims to that of the PURE system). If Applicant feels that a telephone interview would facilitate the prosecution of the present application then the Applicant is invited to contact the Examiner to discuss such matters.
11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Suzanne M. Mayer, Ph.D. whose telephone number is 571-272-2924. The examiner can normally be reached on Monday to Friday, 8.30am to 5.00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon Weber can be reached on 571-272-0925. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

*Smm*  
SMM  
03 May, 2005

  
ROBERT A. WAX  
PRIMARY EXAMINER  
*Art Unit 1653*